K020541
1 of 2

MAY 2 0 2002

510(k) Summary
Agility Ankle Revision Prosthesis

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
(219) 371-4907

B. Device Information:

Proprietary Name:	Agility Ankle Revision Prosthesis
Common Name:	Ankle Prosthesis
Classification Name and Regulatory Class:	Ankle Joint metal/polymer semi-constrained cemented prosthesis: Class II per 21 CFR §888.3110
Product Code:	87 HSN

C. Indications for Use:

Total ankle arthroplasty is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post traumatic or degenerative arthritis.

The Agility Ankle Revision Prosthesis is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The Agility Ankle Prosthesis is intended for cemented use only.

510(k) Summary
Agility Ankle Revision Prosthesis (continued)

D. Device Description:

The Agility Ankle Revision Prosthesis is a modular ankle prosthesis that is comprised of a tibial tray, a polyethylene tibial insert and a revision talar component. The Agility Ankle revision talar component is designed to replace the Agility Ankle primary talar component in revision ankle arthroplasty. It is designed for use with the existing Agility Ankle tibial tray and either the existing polyethylene tibial insert or revision (+2) tibial insert.

The distal surface of the Agility Ankle revision talar component is a rectangular shape and is designed with a fin in the anterior-posterior plane to be cemented into the bone. This distal surface and fin are porous coated with Porocoat. The superior surface is a convex shaped and highly polished to articulate with the polyethylene tibial insert.

The Agility Ankle revision (+2) tibial insert component is manufactured from Ultra High Molecular Weight Polyethylene. It is designed to slide into the existing Agility Ankle tibial tray and is designed to articulate with either the primary or revision Agility Ankle talar components. As with the current tibial insert, the revision insert is designed with lateral and medial ears that slide into the grooves of the tibial tray. The only difference is that the revision insert is 2mm thicker to allow the insert to be used in revision cases and in primary cases where the soft tissues surrounding the ankle are lax.

E. Substantial Equivalence:

The substantial equivalence of the Agility Ankle Revision Prosthesis is demonstrated by its similarity in indications for use, design, materials, sterilization and packaging to the Agility Ankle cleared in K920802 (formerly called the Alvine Ankle).

The determination of substantial equivalence for this device was based on a detailed device description, and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2002

Ms. Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
Depuy Orthopaedics Incorporated
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988

Re: K020541
Trade Name: Agility Revision Ankle
Regulation Number: 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Class: II
Product Code: HSN
Dated: February 18, 2002
Received: February 19, 2002

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K020541

Device Name **Agility Ankle Revision Prosthesis**

Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020541